DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities:

Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the revised information collection project "**The AHRQ Safety Program for Methicillin-Resistant *Staphylococcus aureus* (MRSA) Prevention**."

DATES: Comments on this notice must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

AHRQ Safety Program for Methicillin-Resistant Staphylococcus aureus (MRSA) Prevention

The Agency for Healthcare Research and Quality (AHRQ) requests to revise the currently approved AHRQ Safety Program for Methicillin-Resistant Staphylococcus aureus (MRSA) Prevention. The AHRQ Safety Program for MRSA Prevention's purpose is to reduce the incidence and prevalence of infections caused by MRSA in a variety of settings.

The AHRQ Safety Program for MRSA Prevention was last approved by OMB on August 31, 2021 and will expire on August 31, 2024. The OMB control number for the AHRQ Safety Program for MRSA Prevention is 0935-0260. All of the supporting documents for the current AHRQ Safety Program for MRSA Prevention can be downloaded from OMB's website at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202107-0935-003.

The revision for the AHRQ Safety Program for MRSA Prevention includes the following modifications:

1. ICU/Non-ICU cohort: The optional point prevalence data will be collected at baseline (pre-intervention) and every six months throughout the 18-month implementation period rather than only at baseline. Thus, it will be collected a total of four times. The clinical outcomes measures for the ICU/Non-ICU cohort have been updated from the version included in the original OMB review.

In addition to the change in the frequency of collection of point prevalence data, the program will accept hospital data collected using the new Version 2.0 of the AHRQ Hospital Survey on Patient Safety Culture (HSOPS) as an alternative to the

original HSOPS Version 1.0. HSOPS Version 2.0 is a shorter instrument with a total of 40 survey items compared with 51 survey items in the HSOPS Version 1.0.

2. Surgical Services cohort: After a discussion with the program's Technical Expert Panel (TEP), it was decided to collect surgical site infection (SSI) outcome data on a different subset of surgical procedures performed within the cardiac surgery, orthopedic surgery, and neurosurgery specialty areas. The clinical outcomes measures for the Surgical Services cohort have been updated from the version included in the original OMB review to reflect the changes in surgical types.

For all three surgical specialties, hospitals will have the opportunity to confer rights to the program to their SSI data submitted via National Healthcare Safety Network (NHSN). Hospitals confer rights to their NHSN data by giving the program permission to access their data directly from NHSN. In addition, hospitals with cardiac surgery teams enrolled in the program will be asked to provide data elements that are regularly collected and submitted to the Society of Thoracic Surgeons (STS). STS data elements for cardiac surgeries will include procedures that involve sternotomy and hospital readmission due to Endocarditis, infection (conduit harvest site), infection (deep sternum/mediastinitis), Pneumonia, Sepsis, or wound (drainage, cellulitis).

We estimate that 50% of 300 enrolled units (n=150) will be orthopedic and neurosurgical specialties that will confer NHSN data rights to the program. These hospitals will not need to submit any data directly to the program.

The remaining 50% of 300 enrolled units (n=150) are estimated to be either cardiac surgical specialties that need to submit STS data or orthopedic or neurosurgical specialties that do not confer NHSN data rights to the program. These hospitals are assumed to have some burden for either pulling and submitting STS data extracts for cardiac surgical specialties or pulling and submitting NHSN data elements for orthopedic

or neurosurgical specialties that do not confer rights to NHSN. We assume 1 hour for the initial data pull and 30 minutes for each subsequent quarterly data pull.

In addition to the changes in clinical outcomes described above, the program will use the new HSOPS Version 2.0 instead of the original HSOPS Version 1.0 to assess patient safety culture within enrolled surgical services teams.

3. Long-Term Care (LTC) cohort: The LTC cohort will now also submit the Minimum Data Set (MDS) 3.0 M Skin Conditions data elements. These elements are currently collected by CMS-certified LTC facilities to remain compliant. Since the MDS 3.0 data is already being collected for CMS, LTC facilities would be asked to submit the same data to the program after transmittal to CMS. As a result, there is a minimal change in burden (i.e., from five hours to six hours for the initial data pull and from 30 minutes to 45 minutes for additional pulls). The clinical outcomes measures for the LTC cohort have been updated from the version included in the original OMB review.

The project is being conducted by AHRQ through its contractor, Johns Hopkins University (JHU) and JHU's subcontractor, NORC at the University of Chicago. The project is being undertaken pursuant to AHRQ's mission to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions (42 U.S.C. 299).

Method of Collection

The data collection will include both primary and secondary data sources. The primary data collection includes the following:

1) Unit -level clinical outcome change data: The program will use a secure online portal to collect clinical outcomes measures extracted from site electronic health record (EHR) systems for the 12-month period prior to the start of the implementation, as well as for the 18-month implementation period. These data will be used to evaluate the effectiveness of the AHRQ Safety Program for MRSA Prevention. The clinical outcomes measures for the ICU/non-ICU and Surgical Services and Long-Term Care cohorts have been updated from the version included in the original OMB review.

For the ICU and non-ICU cohorts, the clinical outcomes data will be collected quarterly and will include:

- Hospital onset MRSA invasive infection (MRSA bacteremia LabID Day 3 or after of admission)
- Community onset MRSA invasive infection (MRSA bacteremia LabID prior to Day 3 after admission)
- Patient days
- Central Line-Associated Blood Stream Infections with causative organism(s)
- Central Line Days
- Hospital onset bacteremia (Day 3 or after of admission) with causative organisms, including MSSA
- MRSA-positive clinical cultures

In addition, hospitals that are already conducting MRSA point prevalence surveys in participating ICU and non-ICU units will be asked to submit this optional data via the secure online portal. Hospitals will be asked to submit baseline data at the start of the

program and then submit data once every six months for the duration of the 18-month implementation period. Thus, it will be collected a total of four times.

For the surgical services cohort, the clinical outcomes data will be collected quarterly and will include:

- Surgical site infection (SSI) events and causative organisms
- Number of surgical procedures performed, by type of surgical procedure
- Hospital readmissions

For the LTC cohort, the clinical outcomes data will be collected monthly via the secure online portal, or via fax submission, and will include:

- Transfer of facility resident(s) to an acute care hospital, with reason of suspected or confirmed infection
- Transfer of facility resident(s) to an acute care hospital, with reason other than infection
- All-cause bacteremia with causative organisms
- Resident days
- MDS 3.0 Section M Skin Conditions data elements

2) Survey of Patient Safety: The program will administer AHRQ Surveys of Patient Safety Culture to all eligible AHRQ Safety Program for MRSA Prevention staff at the participating units or facilities at the beginning (month 1) and end (month 18) of the implementation. We will administer the Hospital Survey of Patient Safety Culture (HSOPS) in the ICU, non-ICU, and surgical cohorts, and the Nursing Home Survey on Patient Safety (NHSOPS) in the LTC cohort. We will accept either HSOPS Version 1.0

or Version 2.0 for the ICU and non-ICU cohort and will accept HSOPS Version 2.0 for the surgical services cohort. These surveys ask questions about patient safety issues, medical errors, and event reporting in the respective setting. The program will request that all staff on the unit or facility that is implementing the AHRQ Safety Program for MRSA Prevention complete the survey. As unit and facility size vary, we estimate the average number of respondents to be 25 for each unit.

3) Infrastructure Assessment Tool- Gap Analysis: The program will administer the Gap Analysis at month 1 and month 18 of the implementation to an Infection Preventionist and one of the unit's team leaders (most likely a nurse). Information on current practices in MRSA prevention on the unit will be collected. The Gap Analysis for the surgical services cohort has been updated from the version included in the original OMB review.

4) Implementation Assessments- Team Checkup Tool: The implementation assessments will be conducted to monitor the program's progress and determine what the participating sites have learned through participating in the program. The Team Checkup Tool will be requested monthly, and we anticipate participation from approximately 1 frontline staff (most commonly a nurse) per unit. The program will use the Team Checkup Tool to monitor key actions of staff. The Tool asks about use of safety guidelines, tools, and resources throughout three different phases: Assessment; Planning, Training, and Implementation; and Sustainment. The Team Checkup Tools for the LTC and Surgical Services cohorts have been updated from the versions included in the original OMB review.

The secondary data collection strategy includes use of NHSN data from hospitals that confer rights to the AHRQ Safety Program for MRSA Prevention to use their NHSN data for the evaluation. NHSN data will serve as secondary data sources for clinical outcomes

in ICU, non-ICU, and surgical services units. Clinical outcome measures in LTC settings are not available in NHSN.

For hospitals that confer NHSN rights to the program for the ICU and non-ICU cohorts, the secondary data will include the five out of seven clinical outcome measures that are available via NHSN:

- Hospital onset MRSA invasive infection (MRSA bacteremia LabID Day 3 or after of admission)
- Community onset MRSA invasive infection (MRSA bacteremia LabID prior to Day 3 after admission)
- Patient days
- Central Line-Associated Blood Stream Infections with causative organism(s)
- Central Line Days

For hospitals that confer NHSN rights to the program for the surgical services cohort, the secondary data will include the two clinical outcome measures that are available via NHSN:

- Surgical site infection (SSI) events and causative organisms
- Number of surgical procedures performed, by type of surgical procedure

Estimated Annual Respondent Burden

Exhibit 1shows the total estimated annualized burden hours for the data collection efforts.

All data collection activities are expected to occur within the three-year clearance period. The total estimated annualized burden is 12,052 hours.

Exhibit 1 Estimated annualized burden hours

Form Name	Number of Respondents +	Number of responses per respondent	Hours per response	Total Burden hours
Survey of Patient Safety Culture				
HSOPS Version 1.0 *(25 respondents per unit, pre- and post-implementation for ICU and non-ICU)*	6667	2	0.25	3334
HSOPS Version 2.0 *(25 respondents per unit, pre- and post-implementation for ICU and non-ICU)*	2500	2	0.21	1050
NHSOPS *(25 respondents per facility, one response per pre- and post-implementation for LTC cohort, 300 facilities total)*	2,500	2	0.25	1,250
Infrastructure Assessment				
Gap Analysis *(1 assessment per unit or facility, pre and post-implementation for all four cohorts, 1,400 sites total)*	467	2	1	934
Implementation Assessments:				
Team Checkup Tool *(1 checklist conducted monthly during the 18 months of implementation for ICU, non-ICU, and Surgical cohorts, 1,100 units total)*	367	18	0.17	1,123
Team Checkup Tool *(1 checklist conducted monthly per facility during the 18 month implementation*	100	18	0.17	306

period for LTC cohort, 300 facilities total)				
Electronic Health Record (EHR) Extracts				
Initial data pull for 10% of hospitals that do not confer rights to their NHSN data - (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	27	1	5	135
Initial data pull for hospital onset bacteremia (including MSSA) and MRSA-positive clinical cultures (not available in NHSN) (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	267	1	3.5	935
Initial data pull for 10% of units that submit point prevalence survey data (*once at baseline for ICU and non-ICU cohorts, 800 units tota*l)	27	1	0.5	14
Subsequent data pull for 10% of units that submit point prevalence data (*every six months during 18 months of implementation for ICU and non-ICU cohorts, 800 units total*)	27	3	0.25	20
Initial data pull for 50% of surgical units that do not confer rights to NHSN data - (*once at baseline for Surgical cohort, 300 settings total*)	50	1	1	50
Initial data pull - (*once at baseline for LTC cohort, 300 facilities total*)	100	1	6	600

Quarterly data collection of monthly data- *(quarterly during 18 months of implementation for ICU and non-ICU, cohorts, 800 units total)*	267	6	0.5	801
Quarterly data collection of monthly data for 50% of hospitals that do not confer rights to their NHSN data (*quarterly during 18 months of implementation for surgical cohorts, 300 units total*)	50	6	0.5	150
Monthly data - *(monthly per facility during 18 months of implementation for LTC cohort, 300 facilities total)*	100	18	0.75	1350
Total	**13,516**			**12,052**

+ The number of respondents per data collection effort is calculated by multiplying the number of respondents per unit by the total number of units. The result is divided by three to capture an annualized number.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete the data collection activities. The total annualized cost burden is estimated to be $554,699,76

Exhibit 2 Estimated annualized cost burden

Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate	Total Cost Burden
Survey of Patient Safety Culture				
HSOPS Version 1.0 *(25 respondents per unit, pre- and post-*	6667	3334	$51.53*	$171,801.02

implementation for ICU and non-ICU cohorts)				
HSOPS Version 2.0 *(25 respondents per unit, pre- and post-implementation surgical cohort)*	2500	1050	$51.53*	$54,106.50
NHSOPS *(25 respondents per facility, one response per pre- and post-implementation for LTC cohort, 300 facilities total)*	2,500	1,250	$51.53*	$64,412.50
Infrastructure Assessment				
Gap Analysis *(1 assessment per unit or facility, pre and post-implementation for all four cohorts, 1,400 sites total)*	467	934	$51.53*	$48,129.02
Implementation Assessments:				
Team Checkup Tool *(1 checklist conducted monthly during 3 months of ramp-up and 15 months of implementation periods for ICU, non-ICU, and Surgical cohorts, 1,100 units total)*	367	1,123	$51.53*	$57,868.19
Team Checkup Tool *(1 checklist conducted monthly per facility during 18 months of implementation for LTC cohort, 300 facilities total)*	100	306	$51.53*	$15,768.18
Electronic Health Record (EHR) Extracts				

Initial data pull for 10% of hospitals that do not confer rights to their NHSN data - (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	27	135	$35.17^	$4,747.95
Initial data pull for hospital onset bacteremia (including MSSA) and MRSA-positive clinical cultures (not available in NHSN) (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	267	935	$35.17^	$32,883.95
Initial data pull for 10% of units that submit point prevalence survey data (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	27	14	$35.17^	$492.38
Subsequent data pull for 10% of units that submit point prevalence data (*every six months during 18 months of implementation for ICU and non-ICU cohorts, 800 units total*)	27	20	$35.17^	$703.40
Initial data pull for 50% of surgical settings that do not confer rights to NHSN data - (*once at baseline for Surgical cohort, 300 settings total*)	50	50	$35.17^	$1,758.50
Initial data pull - (*once at baseline for LTC cohort, 300 facilities total*)	100	600	$35.17^	$21,102.00

Quarterly data - *(quarterly during 18 months of implementation for ICU and non-ICU cohorts, 1,100 units total)*	267	801	$35.17^	$28,171.17
Quarterly data collection of monthly data for 50% of hospitals that do not confer rights to their NHSN data (*quarterly during 18 months of implementation for surgical cohorts, 300 units total*)	50	150	$35.17^	$5,275.50
Monthly data - *(monthly per facility during 18 months of implementation for LTC cohort, 100 facilities total)*	100	1350	$35.17^	$47,479.50
Total	**13,516**	**12,052**		**$554,699,76**

*This is an average of the average hourly wage rate for physician, nurse, nurse practitioner, physician's assistant, and nurse's aide from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

^This is an average of the average hourly wage rate for nurse and IT specialist from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the

collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 18, 2022.

Marquita Cullom,
Associate Director.

[FR Doc. 2022-15627 Filed: 7/20/2022 8:45 am; Publication Date: 7/21/2022]